IN THE SPECIFICATION

Please replace the first sentence of the paragraph beginning at Page 11, Line 24, with the following rewritten sentence:

- - The *Eimeria* strain *Eimeria maxima*-I has been deposited with the American Type Culture Collection (ATCC), 10801 University Blvd., Manassas, Va. 20110-2209 on January 27, 2003, under accession number _____ as patent deposits under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. - -

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REMARKS

1. Claims 1-13 were previously pending. Claims 3-13 were withdrawn from consideration by the Examiner, as being drawn to a non-elected invention. Claims 1 and 2 were rejected by Office Action dated October 22, 2002.

2. Restriction Requirement

In response to Applicant's respectfully calling the Examiner's attention to numerous incorrect statements throughout the Examiner's original restriction requirement (Paper No. 5), the Examiner has now corrected some mistakes found in the original restriction requirement. However, the Examiner has additionally changed the restriction requirement and added a new group, *i.e.*, five groups have replaced the original four groups. The Examiner has indicated that the restriction requirement is **final**. Applicant questions the finality of the restriction requirement. Applicant has not had an opportunity to respond to the new and different restriction requirement set forth by the Examiner in Paper No. 7. Applicant seeks clarification.

In response to restriction under 35 U.S.C. § 121, Group I is provisionally elected with traverse. The restriction requirement is submitted to be improper because the Examiner has incorrectly described the invention and clarification is necessary. Further, it is respectfully pointed out that, according to MPEP 803, in order for a restriction requirement to be proper, two criteria must be met: (1) the inventions must be independent or distinct as claimed, and (2) there must be a serious burden on the examiner if restriction is not required.

The Examiner has now correctly referred to "Group I as Claims 1-2 are drawn to an immunovariant strain of *Eimeria maxima*". However, there are again incorrect statements throughout the restriction requirement. For example, the Examiner has again incorrectly described the claims of Group II. The Examiner states, "Claims 3, 5, 7-8, and 10 are drawn to a vaccine...comprising a concentration of oocysts of ***E. maxima***" (Paper No. 7, Page 2). In fact, it is respectfully pointed out to the Examiner that Claim 3 actually recites "oocysts of ***E. maxima*-I**". Thus, the correct statement would be "Claims 3, 5, 7-8, and 10 are drawn to a vaccine for use in combating coccidiosis in chickens comprising a concentration of oocysts of ***E. maxima*-I**". In addition, the Examiner has incorrectly grouped the claims of Groups II and III. In Applicant's response (July 18, 2002) to the Examiner's original restriction (Paper No. 5), Applicant respectfully pointed out that since Claims 3 5, 7-8, and 10 all recite or refer to a vaccine comprising "oocysts of ***E. maxima*-I**" and Claims 4, 6, 9, and 11 all recite or refer to a vaccine comprising oocysts of **an immunovariant strain of *Eimeria maxima* that corresponds in characteristics to the strain *E. maxima*-I**" all claims actually refer to a vaccine comprising oocysts of an immunovariant strain of *Eimeria maxima* (consistent with Claims 1 and 2 belonging to the same group, Group I). Group II and Group III both are drawn to vaccines requiring the use of oocysts from an immunovariant strain. Because both groups, Group II and Group III, require the use of oocysts from an immunovariant strain, Claims 3, 5, 7, 8, and 10 should not be

separated from Claims 4, 6, 9 and 11. In addition, the Examiner states "Group IV requires the use of immunogens related to other pathogens of poultry whereas Group II does not". However, Claim 7 is found in Group II and Group IV. Clarification is requested. Applicant believes Claims 3-11 should be grouped together, consistent with the grouping of Claims 1 and 2.

The vaccine of Claims 3-11 should be included with the immunovariant strain of Group I because Claims 3-11 merely recite a vaccine comprising the immunovariant strain of Group I and the method of using the vaccine. In addition, it is believed that immunovariant strains of Claims 1 and 2 should be examined along with the method claims, Claims 12-13, of Group V wherein the method of obtaining an immunovariant strain is recited. Therefore, there would be no serious burden on the Examiner to search Claims 3-11 since a search attesting that the immunovariant strains of Group I were novel would also point to the vaccine of Groups II and III and the method of obtaining an immunovariant strain of Group V being novel.

In view of the foregoing, the applicant respectfully requests that the Examiner clarify the incorrect statements of the restriction requirement. The applicant further respectfully requests that the Examiner reconsider the restriction requirement and examine Claims 1-13 together as Group I.

2. Amended Specification:

In response to the Examiner's objection to the specification because the "specification at Page 11 lines 27-28 fails to recite the deposit information with respect to the Accession number and date of deposit", the specification has been corrected with regard to the date of deposit. An accession number has not yet been received from the American Type Culture Collection.

No new matter has been introduced by amendment.

Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Applicants hereby request further examination and reconsideration of the application, in view of the foregoing amendments.

3. • The specification has been objected to regarding references to deposited biological material.
   • Claims 1-2 have been rejected under 35 U.S.C. 112, first paragraph.
   • Claims 1-2 have been rejected under 35 U.S.C. 112, second paragraph.
   • Claims 1-2 have been rejected under 35 U.S.C. 102(b).

Objection

4. In response to the Examiner's objection to the specification because the "specification at Page 11 lines 27-28 fails to recite the deposit information with respect to the Accession number and date of deposit", the specification has been corrected with regard to the date of deposit. An accession number has not yet been received from the American Type Culture Collection.

Rejections of Claims 1-2 under 35 U.S.C. 112, first paragraph

5. The Examiner has rejected Claims 1-2 under 35 U.S.C. 112, first paragraph. The Examiner has quoted the first paragraph of 35 U.S.C. 112, but has **not actually stated** the form paragraph rejecting the claims. Based on the Examiner's rejection, Applicant is assuming that the Examiner intended to include the form paragraph stating the reason for the rejection "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention". The Examiner asserts that the "specification lacks complete deposit information for the deposit of the strain designated *E. maxima*-I", that "it is not clear that cell lines possessing the properties of *E. maxima*-I are known and publicly available or can be reproducibly isolated from nature without undue experimentation", and "because the claims require the *E. maxima*-I strain, a suitable deposit for patent purposes is required" (Paper No. 7, Page 6). The Examiner further states that "[I]f the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required" (Paper No. 7, Page 6).

In accordance with the Examiner's comments, applicant's representative, under her signature and registration number, herein states that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent. Further, the specification discloses the deposit and availability to the public beginning on Page 11, Line 24 and continuing to Page 12, Line 18.

In view of the deposit, the required statement, and the above remarks, it is respectfully requested that the rejection of Claims 1-2under 35 U.S.C. paragraph 112, first paragraph, be withdrawn.

Rejections of Claims 1-2 under 35 U.S.C. 112, second paragraph

6. The Examiner has rejected Claims 1-2 under 35 U.S.C. 112, second paragraph, as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." The Examiner asserts that the term "immunovariant" in claims 1-2 is a relative term which renders the claim indefinite. The Examiner further asserts that "neither the claims nor the specification define immunovariant. It is unclear how little or how much variation is required for a strain to be considered an immunovariant" (Paper No. 7, Paragraph bridging Pages 8 and 9).

Applicant respectfully traverses this rejection; the term "immunovariant" is commonly used and well known in the art. The term "immunovariant" refers to antigenic variation. Thus, proteins, cell lines, and strains of bacteria, viruses, and parasites, as examples, can be immunovariant proteins, cell lines, and strains. The term is commonly used in the art as is shown by the examples found on two websites HighWire (http://highwire.stanford.edu) (8 examples) and Scirus (http://www.scirus.com) (25 distinct examples) and enclosed as Appendix A and Appendix B, respectively. An immunovariant strain of the parasite *E. maxima* is a strain that exhibits immunological variation from the established laboratory strain of *E. maxima.* The instant specification discloses and the instant claims recite particular immunovariant strains of *E. maxima*, *i.e.*, an immunovariant strain designated *E. maxima*-I and an immunovariant strain of *E. maxima* that corresponds in characteristics to the strain *E. maxima*-I. The

characteristics of *E. maxima*-I and an immunovariant strain of *E. maxima* that corresponds in characteristics to the strain *E. maxima*-I are disclosed in the Examples.

7. The Examiner has rejected Claim 2 under 35 U.S.C. 112, second paragraph, as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." The Examiner asserts that "the phrase 'corresponds in characteristics to the strain *E. maxima*-I' in claim 2 is a relative term which renders the claim indefinite. There is no definition of what characteristics are required of strain in order for it to correspond to said strain" (Paper No. 7, Page 9).

Applicant respectfully traverses this rejection; the phrase "corresponds in characteristics" is conventional claim language and is commonly used and well known in the art. The word "characteristic" according to Webster's II New Riverside Collegiate Dictionary (1995. Houghton Mifflin Company, Boston, MA, see Appendix C) is defined as "a distinguishing attribute or element" (Page 187). Therefore, in Claim 2, "corresponds in characteristics" refers to distinguishing attributes or elements by which the strains are distinctly recognizable or known, *i.e.*, those characteristics which are commonly shared, including physiological, morphological, and chemically-based characteristics. The claims are read in light of the specification and the qualities and properties of the strains of the invention are set forth in the examples. In addition, other strains, *e. g.*, strains which could be identified by these same characteristics would be considered to "correspond in characteristics".

In view of the above amended claims and remarks, it is respectfully requested that the rejection of Claims 1-2 under 35 U.S.C. paragraph 112, second paragraph, be withdrawn.

Rejection of Claims 1-2 under 35 U.S.C.102 (b) Over Barta et al.

8. The Examiner has rejected Claims 1-2 under 35 U.S.C. 102 (b) as being anticipated by Barta *et al.* (International J. for Parasitology, Vol. 28, pp. 485-492, 1998).

The Examiner states that "Barta *et al.* teach obtaining the *E. maxima* Guelph and Maryland strains which were confirmed as being *E. maxima* by microscopic examination". The Examiner further asserts that "the prior art *E. maxima* Guelph and Maryland strains appear to be the same as that claimed immunovariant strains. The *E. maxima* Guelph and Maryland strains appear to possess the same functional characteristics." The Examiner concludes that "therefore, Barta *et al.* teach an immunovariant strain of *Eimeria maxima*, and an immunovariant strain of *Eimeria maxima* that corresponds in characteristics to the strain *E. maxima*-I as claimed by the instant application" (Paper No. 7, Paragraphs bridging Page 9 and Page 10).

Applicant respectfully traverses the rejection. It is stated in the MPEP (MPEP 2131) that "[A] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" and that "[T]he identical invention must be shown in as complete detail as is contained in the ... claim."

The claims recite a **specific** immunovariant strain ***E. maxima*-I** which has been deposited at the American Type Culture Collection and immunovariant strains having **characteristics corresponding to *E. maxima*-I**. Barta *et al.* do not disclose strains having the same characteristics as *E. maxima*-I. Microscopic examination as taught by Barta *et al.* does not identify immunological variability. As disclosed in the specification, *E. maxima* -I is "totally immunovariant from the *E. maxima*-GPL. Birds immunized

against the Guelph strain no longer recognized the resulting immunovariant *E. maxima* strain, *E. maxima* -I (Page 14, Lines 21-23). The instant specification further discloses "the derived parasite strain, *E. maxima* -I, behaved similarly in both the Guelph strain-immunized and naïve birds suggesting that all or most immunologically relevant cross reactive epitopes had been selected against" (Page 15, Lines 7-9). In addition, Table 1 of Example 5 (Page 16 of the instant specification) illustrates that *E. maxima* -I and the Guelph strain are not one and the same. Whereas immunization with *E. maxima*-GPL protects against challenge with *E. maxima*-GPL and immunization with *E. maxima*-I protects against challenge with *E. maxima*-I, immunization with *E. maxima*-GPL does not protect against challenge with *E. maxima*-I (Table 1, Page 16). Similarly, Table 2 (Page 18) shows that *E. maxima* -GPL immunization did not protect against *E. maxima*-I challenge, and *E. maxima*-I immunization did not protect against *E. maxima*-GPL challenge. Given these facts, *E. maxima*-I and the Guelph strain cannot be one and the same; the prior art *E. maxima* Guelph strain is not the same as that claimed immunovariant strains.

The Examiner's further assertions that the prior art *E. maxima* Maryland strain appears to be the same as the claimed immunovariant strains and that the *E. maxima* Maryland strain appears to possess the same functional characteristics is similarly incorrect. Barta *et al.*, citing a study by Martin *et al.* (Int. J. Parasitol. 27:527-533, 1997; Ref. 4 in Barta *et al.*) teach that "[I]n the same study, infection with one of the North Carolina, USDA 68 or Guelph strains of *E. maxima* was shown to be able to protect birds against challenge with any of these three strains" (Page 491, Left Column, Lines 2-4). However, as stated above, immunization with *E. maxima*-GPL does not protect against challenge with *E. maxima*-I. Thus, again *E. maxima* Guelph cannot be *E. maxima*-I or an immunovariant strain having characteristics corresponding to *E. maxima*-I. Further, in the same Martin *et al.* study (Ref. 4 in Barta *et al.*), Martin *et al.* teach "in Trial 2, birds inoculated previously with GS (Guelph), MD, 68 or NC were protected against challenge with GS" (Martin *et al.*, Page 529, Right Column, Lines 2-4). Thus, if birds inoculated

previously with Maryland were protected against challenge with Guelph, *E. maxima* Maryland cannot be *E. maxima*-I or an immunovariant strain having characteristics corresponding to *E. maxima*-I because again, as stated above, the specification (Table 2, Page 18) discloses that *E. maxima*-I immunization did not protect against *E. maxima*-GPL challenge.

In view of the above remarks, it is respectfully requested that the rejection of Claims 1-2 under 35 U.S.C. 102 (b), be withdrawn.

Rejection of Claims 1-2 under 35 U.S.C.102 (b) Over Martin et al.

9. The Examiner has rejected Claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Martin *et al.* (International J. for Parasitology, Vol. 27 (5), pp. 527-533, 1997).

The Examiner asserts that "Martin *et al.* teach the analysis of immunological cross-protection of five strains of *Eimeria maxima*. The strains of *Eimeria maxima* included the GS (Guelph laboratory strain) and 68 (USDA laboratory strain) along with a Maryland, North Carolina and Florida strains... All strains were confirmed to be *Eimeria maxima* by microscopic examination and isoenzyme analysis... The GS, 68, and North Carolina strains elicited cross-immunity in chickens. Moreover, the GS, 68, and NC strains showed immunological similarities" (Paper No.7, Page 10). The Examiner further asserts that "the prior art *E. maxima* GS, 68 and North Carolina strains appear to be the same as immunovariant strains. The prior art *E. maxima* GS, 68 and North Carolina strains appear to possess the same functional characteristics" (Paper No.7, Paragraph bridging Pages 10-11). The Examiner concludes that "therefore, Martin *et al.* teach an immunovariant strain of *Eimeria maxima*, and an immunovariant strain of

Eimeria maxima that corresponds in characteristics to the strain *E. maxima*-I as claimed by the instant application" (Paper No. 7, Page 11).

Applicant respectfully traverses the rejection. It is stated in the MPEP (MPEP 2131) that "[A] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" and that "[T]he identical invention must be shown in as complete detail as is contained in the ... claim."

The instant claims recite a **specific** immunovariant strain ***E. maxima*-I** which has been deposited at the American Type Culture Collection and immunovariant strains having **characteristics corresponding to *E. maxima*-I**. Martin *et al.* do not disclose strains having the same characteristics as *E. maxima*-I. As disclosed in the specification, *E. maxima* -I is "totally immunovariant from the *E. maxima*-GPL. Birds immunized against the Guelph strain no longer recognized the resulting immunovariant *E. maxima* strain, *E. maxima* -I (Page 14, Lines 21-23). The instant specification further discloses "the derived parasite strain, *E. maxima* -I, behaved similarly in both the Guelph strain-immunized and naïve birds suggesting that all or most immunologically relevant cross reactive epitopes had been selected against" (Page 15, Lines 7-9). In addition, Table 1 of Example 5 (Page 16 of the instant specification) illustrates that *E. maxima* -I and the Guelph strain are not one and the same. Whereas immunization with *E. maxima*-GPL protects against challenge with *E. maxima*-GPL and immunization with *E. maxima*-I protects against challenge with *E. maxima*-I, immunization with *E. maxima*-GPL does not protect against challenge with *E. maxima*-I (Table 1, Page 16). Similarly, Table 2 (Page 18) shows that *E. maxima* -GPL immunization did not protect against *E. maxima*-I challenge, and *E. maxima*-I immunization did not protect against *E. maxima*-GPL challenge. Given these facts, *E. maxima*-I and the Guelph strain cannot be one and the same; the prior art *E. maxima* Guelph strain is not the same as that claimed

immunovariant strains.

The Examiner's further assertions that the prior art *E. maxima* GS, 68 and North Carolina strains appear to be the same as immunovariant strains and that prior art *E. maxima* GS, 68 and North Carolina strains appear to possess the same functional characteristics is incorrect. Martin *et al.* teach that "in both trials, 68, NC and GS were cross-protective and immunization with any one provided protective immunity against challenge with any of the others, as measured by their ability to maintain weight gain and reduce lesion scores relative to the sham immunized and challenged controls (Page 531, Right column, Lines 30-35). However, as stated above, immunization with *E. maxima*-GPL does not protect against challenge with *E. maxima*-I. Thus, *E. maxima* GS, 68, or North Carolina cannot be *E. maxima*-I or an immunovariant strain having characteristics corresponding to *E. maxima*-I.

In view of the above remarks, it is respectfully requested that the rejection of Claims 1-2 under 35 U.S.C. 102 (b), be withdrawn.

Drawings

10. In response to the objections cited by the Draftsperson on PTOL-948, proposed drawing corrections are enclosed with this response.

CONCLUSION

In view of the above remarks, it is believed that all of the claims and the specification are in condition for allowance. Accordingly, it is respectfully requested that the rejections be withdrawn and that the instant application be allowed to issue. If any

issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

March 24, 2003
Date

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

The paragraph beginning at Line 24 of Page 11 has been amended as follows:

The *Eimeria* strain *Eimeria maxima*-I has been deposited with the American Type Culture Collection (ATCC), 10801 University Blvd., Manassas, Va. 20110-2209 on January 27, 2003, ~~2001~~ under accession number ________ as patent deposits under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

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* Evelyn M. Rabin *
* (Name of applicant, assignee, or Registered Representative) *
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* Evelyn M. Rabin March 24, 2003 *
* (Signature) (Date) *
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